

FDA Webinar: Accreditation Scheme for
Conformity Assessment (ASCA) Pilot Program: Draft Guidance

Moderator: Irene Aihie
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12:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time all participants will be on a listen-only mode until the question and answer session of today's call. At that time please press star followed by the number 1, un-mute your line, and record your name clearly as prompted to be introduced.

Today's conference is also being recorded. And if you have any objections you may disconnect. I'd like to introduce Irene Aihie. Ma'am you may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie, of CDRH's Office of Communication and Education. On September 23, 2019, the FDA issued a Draft Guidance on the Accreditation Scheme for Conformity Assessment Pilot Program. The ASCA Pilot is intended to support the FDA's public health mission by providing increased confidence in testing from ASCA-accredited testing laboratories, as well as potentially decreasing the burden of individual premarket submissions when manufacturers rely on testing completed by ASCA-accredited testing laboratories. The webinar will provide details about the draft guidance and offer an opportunity for webinar participants to ask questions about the draft guidance.

Today, Stacy Cho, Senior Policy Analyst, in the Office of Strategic Partnerships and Technology Innovation, here in CDRH, will present an overview of the draft guidance document. Following the presentation, we will open the line for your questions related to information provided during the presentation. Additionally, there are other Center subject matter experts here with us today to assist with the Q&A portion of our webinar.

Now, I give you Stacy...

Stacy: Hello everyone. Thank you for joining us. And thank you Irene for the introduction.

Again my name is Stacy Cho. And as Irene stated I will be discussing the recently published draft guidance, the Accreditation Scheme for Conformity Assessment Pilot Program. Our agenda for today is to go over the objectives of this training session, background information, and overview of the ASCA pilot program.

We will discuss the roles and responsibilities of the different stakeholders. The selected device standards, pilot participation, the ASCA program specifications, and pre-market review considerations. We will conclude with stakeholder information including the timeline of the guidance commenting period.

Through today's session we hope to clearly convey why ASCA is being developed, how ASCA is being developed, and explain to you what ASCA will be. This webinar will go over the roles of all stakeholders. How external stakeholders can participate in the program and its impact on pre-market review.

During negotiations for MDUFA IV, FDA and Industry agreed to establish a conformity assessment accreditation scheme for testing laboratories that evaluate medical devices according to certain FDA recognized standards. FDARA amended section 514 of the Food Drug and Cosmetic Act by adding a new sub-section D titled Pilot Accreditation Scheme for Conformity Assessment. And this is the regulatory foundation for the pilot program.

Please note that the draft guidance is distributed for comment purposes only. The program will be operationalized upon publication of the final guidance. While we discuss the regulatory foundation of ASCA I'd like to delve further on why the ASCA pilot program is being developed.

Evidence of conformity to one or more FDA recognized standards is often a thorough and efficient way for a manufacturer to address certain questions of safety and or effectiveness. This is why FDA invests time and personnel into participating into various standard working groups so that the agency may have input in the development of these different medical standards. For manufacturers and FDA to benefit from this efficiency FDA must have confidence in the Declaration of Conformity or DOC, submitted by device manufacturers in their pre-market submissions.

This is described in the final guidance document titled *Appropriate Use of Voluntary Consensus Standards and Pre-Market Submissions for Medical Devices*. While the appropriate use guidance document describes the different types of information needed for medical device testing to determine safety and or effectiveness, in practice the reliability of the determination in the DOC varies depending on the specific laboratory performing the testing and the standard being used. These differences between testing laboratories and how they conduct the testing in some instances results in the need for FDA to request additional information, review complete test reports, or repeat testing.

And this causes delays and additional costs. This is where the ASCA pilot comes in. The ASCA pilot program capitalizes on the relevance of consensus standards and device development and regulatory review and the existence of a well-established international conformity assessment infrastructure. The ASCA pilot program aims to improve efficiency of the pre-market review process by building confidence in the declaration of conformity through the utilization of accredited testing laboratories. FDA has not previously had a relationship with testing laboratories.

But through the ASCA pilot program we hope to change this by opening up a relationship with testing laboratories through accreditation bodies. We establish the why but let us now discuss how the program is being developed. As mentioned earlier the concept of the ASCA pilot program emerged from discussions between device manufactures and FDA resulting in the MDUFA IV and FDARA.

FDA then published the Federal Register Notice in May of 2017 requesting comments on a set of questions designed to gain insight regarding development and overall design of the ASCA pilot program. We then took that information and held a public workshop the following year. The workshop took place over two days on May 22 and 23rd in 2018.

And we invited testing laboratories, accreditation bodies, and device manufacturers to open discussion across these different stakeholders and FDA. Throughout this time and even now, a conformity assessment expert from the National Institute of Standards and Technology is working with CDRH to develop the ASCA pilot program. This expert is the co-author of the following NIST paper:

Conformity Assessment Consideration for Federal Agencies. This expert has helped multiple Federal Agencies set up conformity assessment programs ranging from OSHA to GSA. We will now delve into the overview of what the ASCA pilot program is.

To ensure that we all start-off with the same knowledge base, and to not assume everyone is familiar with conformity assessment, these are the following definitions from ISO/IEC17000 regarding Conformity Assessment. Conformity assessment is the demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled. Conformity assessment body is a body that performs conformity assessment services such as a testing laboratory.

Note that an accreditation body is not a conformity assessment body. A conformity assessment scheme is a conformity assessment system related to specified objects of conformity assessment to which the same specified requirements, specific rules, and procedures apply. An element of the ASCA pilot program is the accreditation body.

So what is accreditation? Accreditation is a third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

An accreditation body is as an authoritative body that performs accreditation. And third-party attestation is an issue of statement based on the decision, following review, that fulfillment of specific requirements has been demonstrated. So what will the ASCA pilot be?

First we want to emphasize that this will be a voluntary program for all external stakeholders, which are the accreditation bodies, testing laboratories, and device manufacturers. Given that the ASCA pilot participation qualifications for these external stakeholders have been met, the following two columns show what FDA intends and does not intend to do in the pilot program.

So FDA intends to leverage the existing relationships between accreditation bodies and testing laboratories. We do not want to re-invent the wheel. But we do want to see where FDA can fit to increase efficiency and confidence wherever possible.

FDA intends to rely on recognized accreditation bodies to accredit testing laboratories using a specific conformity assessment scheme

outlined in this guidance. Please note we will discuss this scheme a bit later in the presentation. FDA intends to generally accept the testing laboratory's determination that a device conforms with the specified standards based on the increased confidence testing laboratory's determination.

FDA does not intend to question the validity of methods and outcomes from ASCA-accredited testing laboratories except in the following instances: as part of periodic audits, if the summary test reports indicate an issue with the testing or device, or FDA becomes aware of information materially bearing on the safety or effectiveness of the device. This is a diagram showing the proposed process flow of the ASCA pilot program.

Please note that ABs refer to accreditation bodies. And TLs refer to testing laboratories. Accreditation bodies voluntarily apply to participate in the pilot.

FDA then reviews the application and recognizes qualified accreditation bodies for participation in the pilot. FDA then shares the list of participating accreditation bodies. This allows testing laboratories to choose an accreditation body from the list.

The testing laboratory then goes through the entire accreditation body-accreditation process. After receiving accreditation from the recognized accreditation body, testing laboratories may then apply to participate in the ASCA pilot. FDA then reviews the testing laboratory's application.

FDA recognizes qualified testing laboratories for ASCA pilot participation and grants *ASCA Accreditation*. FDA shares the list of participating testing laboratories. This allows device manufacturers to select ASCA-accredited laboratories.

Device manufacturers will then be allowed to use summary test reports in pre-market submissions from ASCA-accredited testing laboratories. So I know that that was a lot of material. And the next two slides will help break down the information.

So this slide is to help you understand the differences between recognition and accreditation as proposed in the draft guidance since there is a distinction between the two. We'll acknowledge that the terms recognition and accreditation hold specific meanings outside of the scope of ASCA but I'd like to hone in on what these two terms are proposed to mean within the pilot program. So for

the purposes of the pilot program FDA recognizes accreditation bodies and testing laboratories as participating in the ASCA pilot.

These recognized accreditation bodies and recognized testing laboratories receive trainings from, regularly communicate with, and are periodically audited by FDA. Recognition is provided to any qualified applicant organization that agrees to the terms of participation. And we will go over these qualifications and terms in a few slides.

The scope of recognition refers to the standards and test methods for which competence in accreditation or testing has been demonstrated to FDA for the purposes for the pilot program. The second term is accreditation. FDA uses the term accreditation for a testing laboratory in two different contexts within the pilot program: by an accreditation body, and *ASCA-Accreditation* by FDA. Accreditation by an accreditation body is how the conformity assessment world typically uses this term as previously defined in the presentation. Accreditation bodies accredit laboratories to specifications of ISO/IEC 17025 and ASCA program specifications.

ASCA-Accreditation by FDA is a term used to describe FDA's acceptance of accreditation to ISO/IEC 17025 which is a standard that outlines the requirements for competence in testing labs and the ASCA program specifications outlined in the draft guidance by a recognized accreditation body. This exists only within the ASCA pilot program and only testing laboratories recognized by FDA as participating in the ASCA pilot program may receive *ASCA-Accreditation*.

FDA intends to generally accept testing results from an ASCA-accredited testing laboratory in pre-market submissions without further interactions concerning testing methods except in specific circumstances. So as a quick recap to the different terms used in the proposed process flow of the pilot program: accreditation bodies may apply to participate in the pilot. FDA then recognizes qualified accreditation bodies for pilot participation.

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Testing labs then receive accreditation from recognized accreditation bodies which reflects the first context described in the previous slide. This is referring to accreditation that's typically in the conformity assessment world. Testing laboratories may then apply to participate in the ASCA pilot with the accreditation they received from a recognized accreditation body.

FDA then recognizes qualified testing laboratories for ASCA pilot participation and *ASCA Accreditation*. This is the second context described before with the term *ASCA Accreditation* only existing within the pilot program.

Device manufacturers may select ASCA-accredited testing laboratories for testing and use the summary test reports in pre-market submissions. How would the ASCA pilot leverage existing conformity assessment resources?

It was stated that FDA does not want to reinvent the wheel. Therefore, we intend to maximize the use of existing frameworks and arrangements for the ASCA pilot wherever possible. The first framework we intend to leverage is the ILAC MRA, or the International Laboratory Accreditation Cooperation Mutual Recognition Agreement. ILAC is an international organization for accreditation bodies that accredit conformity assessment bodies such as testing laboratories. Accreditation bodies that are signatories to the ILAC MRA are peer evaluated to ISO/IEC 17011 to demonstrate their competence.

ISO/IEC 17011 include specifications for accreditation bodies. And it is titled Conformity Assessment Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies. So how will ASCA leverage the ILAC MRA?

Well in the ASCA pilot program accreditation bodies must have ILAC MRA signatory status in order to qualify for participation. FDA intends to leverage ILAC MRA policies and procedures including their peer evaluations. FDA also intends to leverage 17011 policies and procedures including testing laboratories assessments that are laid out in this standard.

The second framework that FDA intends to leverage is ISO/IEC 17025. This standard contains specifications for laboratories to operate competently and generate valid results. The title of 17025 is General Requirements for the Competence of Testing and Calibration Laboratories.

Accreditation bodies that are signatories to the ILAC MRA already accredit testing laboratories to ISO/IEC 17025. In the ASCA pilot we intend to leverage this framework by utilizing accreditation bodies to use ISO/IEC 17025 plus ASCA program specifications outlined in the draft guidance to accredit testing laboratories. FDA intends to leverage the policies and procedures of 17025 including annual internal audits conducted by testing laboratories.

Which device standards is the FDA considering? We would like to emphasize that the pilot is only for selected standards and is not a program that is going to be applicable to all medical device standards across the board. FDA identified standards for the ASCA pilot program based on the input at the public workshop and in response to Federal Register Notice back in 2017 and 2018. In accordance with the MDUFA IV commitment letter, these standards include both cross-cutting or horizontal and device specific or vertical standards. That have public health significance and have or are able to provide the means for establishing acceptance.

The first set of standards are what we refer to as the 60601 family or basic safety and essential performance of medical electrical equipment, medical electrical systems, and laboratory equipment family. This covers 60601-1, along with the FDA recognized collateral and particular standards in the 60601 family. This also would include IEC 61010-1 and its family of FDA recognized particular standards.

The second set of standards in the pilot is the biological evaluation of medical devices. This includes the specific list of tests within the ISO 10993 family, such as complement activation, direct and indirect hemolysis, MEM elution cytotoxicity, intracutaneous Reactivity Irritation, Guinea Pig Maximization Sensitization, and Closed Patch Sensitization, acute systemic toxicity, material immediate pyrogenicity, and sample preparation for all test types. 17025 served as the foundation for the proposed ASCA program specifications found in Appendix A and B of the draft guidance. The working groups consisted of technical experts and personnel from FDA and NIST.

To give you a better idea of how this was established, these three images are excerpts of section 7.2 of the 17025 standard. The second column is section 7.2 of the ASCA program specifications for the biological evaluation of medical devices. And the third column is section 7.2 of the ASCA program specifications for the basic safety and essential performance family.

As you can see, the technical experts and personnel for each working group went through each section of 17025 and added in additional specifications for each of the two standards that we believe will help bolster the confidence in the testing of the selected device standards. This slide shows how each group listed

out program specifications for the selection verification and validation of methods.

This slide gives a nice overview of the proposed roles and responsibilities of the four different stakeholders that make up the ASCA pilot program. We'll start off with the relationship between FDA and accreditation bodies. FDA grants and withdraws recognition, provides training and program updates, and conducts audits. Accreditation bodies maintain qualifications for participation such as maintaining signatory status to ILAC MRA.

Testing laboratories can then request accreditation by recognized accreditation bodies. Testing laboratories are accredited using ISO/ICE 17025 and ASCA program specifications. We'll then move on to the relationship between FDA and testing laboratories. FDA grants and withdraws recognition, grants and suspends *ASCA Accreditation*, provides training and program updates, and conducts audits.

Testing laboratories maintain qualifications for participation, such as maintaining accreditation with the recognized accreditation body. Device manufacturers can then request device testing by an ASCA-accredited testing laboratory. Testing laboratories conduct device testing and provide test reports to the device manufacturer.

We'll then move to the relationship between FDA and device manufacturers. Device manufacturers submit pre-market submission with appropriate information for testing from an ASCA-accredited testing laboratory.

FDA then reviews and provides final decision on the pre-market submission. So what are the proposed participation qualifications for the following two stakeholders? Accreditation bodies should provide proof of signatory status to the ILA mutual recognition agreement and be based in the USA, and they should agree to the terms and conditions described in section D of appendix C in the guidance, which we will discuss in the next slide. These terms and conditions are things like committing to FDA training, maintaining scope of ILAC signatory status, etcetera.

Testing laboratories should ensure that the requested scope of recognition is consistent with the scope of accreditation provided by an accreditation body recognized as an ASCA pilot participant. Testing labs should also agree to terms and conditions described in section D of appendix D in the guidance, which includes

committing to FDA training, and allowing FDA to conduct audits upon requests.

The next four slides provide an overview of the proposed application content for the accreditation body and testing laboratory wishing to participate in the pilot program. Accreditation bodies should provide information such as the point of contact and the requested scope of recognition from the list of selected standards and/or test methods in the pilot. Section C of the application content requests information in support of competence of the accreditation body.

This includes proof of signatory status with ILAC MRA whose scope includes ISO/IEC 17025 and proof that the accreditation body is based in the US. This section also requests description of any current conformity assessment services offered, description of the process that will be used to accredit testing laboratories to 17025 and ASCA program specifications, description of approach to determine technical competency of testing laboratories and description of policy and processes concerning corrective actions. The last section to the proposed accreditation body application is the signed agreement. The accreditation body would agree to maintain ILAC MRA signatory status, verify conformance with ISO/IEC 17025 and ASCA specifications when accrediting testing laboratories, provide all ASCA pilot accreditation documentation and allow FDA to participate as an observer during an ILAC MRA peer evaluation and during the accreditation body's assessment of a testing laboratory. The accreditation body would also agree to commit to all FDA training, and to establish and maintain appropriate communication with FDA. This includes notification of any changes that may impact pilot participation or any changes that may impact participation of any testing laboratory that the accreditation body has accredited. Communication also includes annual status updates, such as any complaints or number of suspensions issued by the accreditation body to a testing laboratory. The accreditation body would also agree to establish and maintain policies and procedures that incorporate feedback from the FDA.

They would acknowledge that FDA maintains complete discretion regarding recognizing an accreditation body's participation in the ASCA pilot, noting that FDA may withdraw recognition at any time. And finally for accreditation bodies to confirm all information submitted to FDA is truthful and accurate and no material fact has been omitted.

The next two slides discuss the proposed testing laboratory application content found in appendix D of the guidance. Testing laboratories would provide information such as their point of contact and their requested scope of recognition from the list of selected standards and or test methods. Section C of the application content requests information in support of competence of the testing laboratory.

This includes proof of testing laboratory accreditation that shows that the accreditation is from the accreditation body that is participating in the ASCA pilot. The scope of recognition for the accreditation body includes the scope for which they accredited the testing laboratory, and scope of accreditation provided by the accreditation body to the testing laboratory matches the testing laboratory's requested scope of recognition. Testing laboratories would also provide a copy of the index of SOPs and any relevant ASCA test related documents applicable to any biological evaluation of medical device standards and/or test methods if it is included in the scope of recognition.

The last section to the proposed testing laboratory application is a signed agreement. The testing laboratory would agree to conduct testing in accordance to ISO/IEC 17025 and ASCA program specifications, abide by ASCA program specifications to achieve and maintain status as an ASCA-accredited testing laboratory and allow FDA to conduct audits upon request. Audits may include observations of testing activities and documentation review. Testing laboratories would also agree to establish and maintain appropriate communication with FDA such as notification of any changes that may impact the testing laboratories' pilot participation, attendance at regularly scheduled teleconferences, and providing annual reports of complaint handling.

Testing laboratories would also agree to commit to attend all FDA training, and ensure proprietary information is protected per client agreements. They would also acknowledge that FDA maintains complete discretion regarding recognizing a testing laboratory's participation and *ASCA Accreditation*, noting that FDA may withdraw recognition or *ASCA Accreditation* at any time.

And finally have testing laboratories confirm that all information is truthful and accurate and no material fact has been omitted. This slide describes the proposed application process for accreditation bodies and testing laboratories. Please note that applications are not ready for receipt at this time. Accreditation bodies and testing

laboratories can submit their application via email to ASCA -- A-S-C-A -- at fda.hhs.gov.

Applications will be reviewed within 60 calendar days. This includes additional information requests, and interactive discussions. The decision of recognition will be emailed to the applicant.

This will include the scope and the date of expiration if recognition is granted. Please note that in order to continue participation in the pilot program, the accreditation body or testing laboratory may apply for renewal of recognition 6 months prior to the expiration date. Recognized participants will be listed on the FDA public website.

This way testing laboratories will be able to choose which accreditation body they would like to receive accreditation from. And manufacturers will be able to choose which testing laboratory they would like to receive testing from. We acknowledge that there may be changes to this scope of recognition.

And there are three possible changes listed below. One: expansion of accreditation body or testing laboratory scope of recognition to include new standards and or test methods. Two: withdrawal of all or part of an accreditation body or testing laboratory scope of recognition. And three: suspension of a testing laboratory's ASCA accreditation. So what is the difference between withdrawal and suspension? Withdrawal is a permanent or broad change of status with respect to the ASCA pilot program.

Withdrawal of recognition means that an organization is no longer a participant in the ASCA pilot. This can be voluntary or initiated by FDA upon becoming aware of information that decreases confidence in the test results. A new application would be needed to participate in the pilot program again.

In other words, submissions that include device testing from a participant that is withdrawn from the ASCA program would go back to quote-unquote regular review, per the appropriate use guidance document discussed earlier. Suspension is a temporary or narrow change of status with respect to the ASCA pilot program. Suspension of ASCA accreditation means that an organization can continue to participate in the ASCA pilot program such as participating in FDA training, but FDA has temporarily invalidated its *ASCA Accreditation* pending the resolution of identified issues.

Suspension can only occur with testing laboratories. Testing labs can respond to a suspension letter, address issues, and reinstate their *ASCA Accreditation* status. In this instance we carefully consider reasons for suspension and deal with submissions with testing from these labs accordingly. For example, if a reason for suspension is strictly administrative information then this would not necessarily affect the confidence in the testing lab results but would affect the terms of participation and therefore need to be rectified before reinstating *ASCA Accreditation*. Requests can be submitted to FDA for clarification on one or more specific ASCA program specifications from a recognized accreditation body or testing laboratory.

This request presents a question relative to the implementation of the ASCA program specifications. This does not include suggestions or request for modifications. These requests for clarifications should be submitted to ASCA@fda.hhs.gov.

Otherwise we recommend comments be provided through the docket which I will discuss in a few slides. FDA intends to periodically audit accreditation bodies and testing laboratories to ensure that they are adequately fulfilling program expectations per section 514(d) of the statute. However, as it appears to be the theme of this training session we plan to leverage existing audits within the conformity assessment world by participating as an observer during audits or reviewing audit reports wherever possible.

So what are the existing audits that already happen now? For accreditation bodies ILAC MRA signatories are subject to peer-review evaluation every 4 years. FDA will participate as an observer during peer evaluations and/or obtain a copy of the report for review.

For testing laboratories they are assessed at least every two years by the recognized accreditation body, so IEC 17011. And they also conduct their own internal audits every year per ISO/IEC 17025. FDA will participate as an observer during these assessments and audits and/or obtain a copy of the report.

FDA does reserve the right to initiate audits if FDA becomes aware of information that raises potential concerns with ASCA pilot program participation. This could be remote or onsite depending on the nature of the concern. This will be a voluntary program for device manufacturers as well.

It does not alter the manufacturer's responsibility to address relevant information in the pre-market submission which includes documenting how the testing supports marketing authorization, even if the testing was conducted by a testing laboratory participating in the ASCA pilot program. The two documents that will have some changes for manufacturers who opt to use an ASCA-accredited lab are the cover letter and declaration of conformity.

As proposed the cover letter should clearly indicate ASCA, the name of the testing laboratory, and its ASCA identifying number. It should also include the standards used for testing the device. Please note that the standards must be a part of the pilot program.

As proposed the declaration of conformity should clearly indicate the date the testing was conducted, the status of *ASCA Accreditation* for testing conducting, because this ensures that *ASCA Accreditation* was not suspended during the time of testing. And the ASCA summary test report. Please appendix E and F for examples.

We would also like to note that this does not alter the manufacturer's responsibility to address relevant information in the pre-market submission as outlined in the *Appropriate Use of Voluntary Consensus Standards in Pre-market Submissions for Medical Devices* guidance document. This includes documenting how the testing supports marketing authorization, even if the testing was including by a testing laboratory participating in the pilot program.

The following slide provides pre-market considerations for FDA staff. FDA intends to align the results from an ASCA-accredited testing laboratory for the purposes of pre-market review provided that FDA is not aware of any information that would result in suspension of *ASCA Accreditation* or withdrawal of recognition and if summary reports, test reports do not indicate an issue with testing or device.

This means the FDA would generally accept the determination that a device conforms with the standards without the need for additional information related to conformance with a standard or review of a complete test report. FDA does not intend to review methodologies for testing conducting by an ASCA-accredited testing laboratory within its recognized scope. FDA does not intend to review complete test reports or request additional

information unless tests' concerning findings or basic administrative information is missing.

And finally FDA does not intend to question the validity of test methods from an ASCA-accredited testing laboratory except as part of periodic audits or if the FDA becomes aware of information materially relevant to the safety or effectiveness of the device. We hope that with teamwork across the four different stakeholders - accreditation bodies, testing laboratories, device manufacturers, and FDA - we will be able to leverage the existing conformity assessment framework to all of our advantage for efficient utilization of medical device testing. Please note that comments on the draft guidance are due by December 23, 2019.

And the link to the docket can be found here. And the following links will be pertinent to your understanding of the pilot. The first is the draft guidance link: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program>.

The ASCA webpage: <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca>. The FDA recognized consensus standards database: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. And appropriate use guidance: <https://www.fda.gov/media/71983/download>. And this will help you understand the ASCA pilot program.

This concludes the presentation portion of the webinar. We will now take questions over the phone. If you have any questions that we cannot get to if you have questions later down the road regarding the ASCA pilot program please email us at asca@fda.hhs.gov.

For more general questions please submit them to [\(dice\)@fda.hhs.gov](mailto:(dice)@fda.hhs.gov). At this time I'd like to introduce the panel of experts present who will also help answer your questions.

Irene Aihie: Operator: we'll take questions.

Coordinator: Thank you. At this time to ask a question please press star followed by the number 1. Again please press star followed by number 1. Un-mute your line, and record your name clearly as prompted to be introduced.

Stacy Cho: I'd like to first introduce Captain (Scott Colburn). He is the Director of the Standards and Conformity Assessment Program at CDRH. Next is (Amy Phelps).

She is a Conformity Assessment Expert from (NIST). And last but not least (Erin Cutts) who is a Senior Policy Analyst and Team Lead of the ASCA program.

Coordinator: One moment for the first question. (Allison Cumiya) your line's open.

(Allison Cumiya): Hi. Thanks so much for this webinar. It's extremely helpful and exciting. I have a question about the appendixes.

In particular Appendix E eligible evaluation of medical devices and the examples that were provided. Does FDA plan to review those from the test labs before a medical device manufacturer would submit them in a pre-market submission? Essentially someone's left them or put them in sort of a master file so FDA knows what to expect when they see this is a (unintelligible) let's say.

(Erin Cutts): Hi this is (Erin Cutts). I'm the ASCA team lead. And I'll try my best to answer the questions and look to my colleagues to add on if needed.

So the example summary test reports are examples of information that would accompany a declaration of conformity in a pre-market submission [per ISO 17050-2]. So they would still be coming in with a 510K, with the IDE, with any other information the manufacturers include in a pre-market submission. Does that address your question?

(Allison Cumiya): I guess my question is more does FDA plan to review the proposed summary during the accreditation lab assessment I guess of the test lab. So, you know, I know these are examples that could be used. Or does FDA I guess expect us or expect test labs to use that appendix almost word for word.

(Amy Cutts): So they are recommendations in the guidance document. And there's in part component of the application review that I think Stacy mentioned in her presentation provides compatibility. In particular FDA will be taking a look at the SOPs and protocols for the tests that are conducted. So we will be reviewing that as part of the review process for testing labs.

(Allison Cumiya): Okay. And just quick follow-up question, so FDA does not plan at this time to do anything or to include absorbable and (plemorizing) devices and liquid devices, is that correct?

(Amy Cutts): That's correct.

(Allison Cumiya): Okay. Thank you so much.

Ilene Aihie: We'll take our next question.

Coordinator: (Ronday) your lines open. You may ask your question.

(Ronday): Hi thank you. Thanks for this webinar. We wanted to understand the relationship about device manufacturers who have their own testing laboratories facilities. Can those testing laboratories that are owned and operated by the device manufacturer be part of this program? Or is this really meant for sort of external third-party laboratories?

Stacy Cho: Hi this is Stacy again. So in this instance we completely acknowledge the fact that there are device manufacturers that own a testing laboratory facility. And we welcome applications across.

(Ronday): Okay. Thank you.

Coordinator: One moment for the next question. (Carol McDonald) your lines open.

(Carol McDonald): Hi thank you. My question was about overseas accreditations. For example if in large we wanted to gain accreditation to ASCA, would the program take account of existing accreditations. For example the UK NHRA Group of Work Practice accreditation?

(Scott Colburn): Hi this is (Scott Colburn). Thank you for your question. So the program is designed to work with the US based accreditation bodies that operate under the ILAC MRA.

And in under that umbrella those accreditation bodies either currently have or have the capacity to accredit testing laboratories that meet the ASCA program specifications that could be either US based or International as well. And we do know of many laboratories that are accredited by a US based ILAC MRA accreditation body that may be outside of the US boundaries. So the potential does exist provided that laboratory is accredited by one of the participating accreditation bodies and is meeting the

criteria that's outlined in the guidance document. Does that answer your question?

(Carol McDonald): Yes it does. Thank you.

Coordinator: Thank you our next question is from (Jeff Ballyns). Your line's open.

(Jeff Ballons): Hi Stacy. Thank you for the excellent presentation. So (Jeff Ballyns).

I actually just had a follow-up question to the one regarding whether or not device manufacturers with their own testing laboratories can participate. So since this is a pilot program the next question is whether or not there is a limit to the number of participants that can be allowed to participate in ASCA pilot.

Stacy Cho: Hi (Jeff). No this is - there is no limit in pilot participation. We are very much aware of the number of testing labs out there. And as I said before we welcome the application so long as the terms of participation are met.

(Jeff Ballons): Thank you very much.

Coordinator: And our next question is from (Robert Burrack) your lines open.

(Robert Burrack): Good afternoon everyone. Thank you for your time and attention on this matter. This is I guess basically a follow-up question from my colleague in the UK concerning the US accreditation bodies.

I'm a bit concerned with international organizations such as my own. You know, we have various accreditation bodies we're using globally that obviously we'd like to be able to leverage their accreditations. But my concern is with utilizing US accreditation bodies, it could add a considerable amount of time and cost to potentially being I guess audited a second time for something that they've already been. Accredited to say by (CNAS) or (COFRAC) in France.

(Scott Colburn): Hi (Robert). This is (Scott Colburn) again. Thank you for the question. Yes this is one of the things we do realize exists.

And it's something that, you know, we're trying to understand under the pilot how we can see it - see in organic growth for, you know, so to speak of the program potentially. But the design of the pilot is for the agency to become familiar with and gain confidence

in the processes that exists. And we have, you know, a starting point of this was what was directed - what they'll find in the ASCA guidance for working with US based accreditation bodies that are in the ILAC.

Understanding how that system works and how the feed into the larger international or global system under ILAC with the MRA. We hope to gain, you know, information on that to see is there the potential in the future. But that right now is not, you know, fully understood until we get the gained experience from what we understand in the pilot.

We understand that that may limit certain laboratories wishing to participate. But again that's one of the things that we had to say where we could start with and then be able to keep our hands around to understand how to best impact the quality of the program.

(Robert Burrack): Yes. That's makes perfect sense (Scott). Thank you.

Coordinator: Thank you. Our next question's from (Michael). Your lines open.

(Michael): Hello.

Coordinator: Yes. Your line's open.

(Michael): All right. Thank you. Thank you for the presentation. Will this affect - so for example when doing the biological evaluation part of the requirement is to do GLP with accredited laboratory.

Do we still have to do a GLP? Or is this going to be a specific format that is going to follow. Thank you.

Woman 1: So the GLP - there's actually several instances where GLP is mentioned and included in our ASCA program specifications. We've thought very carefully about what we need a testing lab to be doing in order to feel confident in their testing. So it's actually mentioned in our ASCA program specifications. And you still need to follow GLP.

(Michael): Okay. Thank you.

Coordinator: Thank you. Our next question is from (Falice Lamaldon). Your line's open.

(Falice Lamaldon) Yes hi. I was wondering how soon will applications open? And when will the program be started?

Woman 2: Thank you for that question. We do have a statutory due date to initiate the pilot by September 30th of 2020. So we're doing everything we can to meet that deadline.

And, you know, if also a little sooner. But that's when we're initiating the pilot.

Coordinator: And (Falice) is that finished with your question? We'll move on to the next...

(Falice Lamaldon): Yes. I'm sorry when will applications be open?

Woman 2: So the applications won't be open until we've initiated the pilot, the final guidance publication.

(Falice Lamaldon): Thank you.

Coordinator: And thank you. Once again to ask question it is star followed by number 1. That is star followed by number 1.

Please ensure to un-mute your line and record your name clearly as prompted to be introduced. And our next question is from (Charles Williams). Your lines open.

(Charles Williams): Hello. Yes. I was wondering if you could speak to the benefit of medical device manufacturers of joining the program voluntarily?

(Amy Cutts): Yes thank you for your question. We actually see a lot of benefits for the medical device manufactures. We are trying to enhance the confidence in testing.

And that's testing that comes in a pre-market submission. So review staff when they're looking at a test report - a summary test report from an ASCA-Accredited lab can have confidence that the test was conducted in the way that we want them to be conducted. So we won't be asking additional information questions about how those test were conducted.

There are - except under some very specific circumstances that Stacy outlined in her slides. So we're expecting for the review to be smoother And for it to be - everyone to have confidence in the testing that's coming into us.

(Scott Colburn): So I would like to add on to that as well that manufacturers either own testing laboratories that are participating or when they engage in contract with an external laboratory participant in the program should have gained confidence themselves in understanding that the FDA has engaged in discussions. Has conducted training, and provided their perspective on how they like to see the information.

That is comprised of the testing report that's brought to the manufacturer and then that is drilled down to an appropriate level of information to support the declaration conformity [per ISO 17050-2] should enhance the confidence of the manufacturer in hoping that the FDA then will see and understand what the purpose of that declaration is serving. And how that helps overall in the - of the review of the medical device as a whole. So there's a lot of enhanced confidence by all stakeholders because of the agency's ability now to engage.

And have, you know, training opportunities. And also this will carry over into future standards, development enhancements for next editions where we will be able to take experience gained through this program and help the overall process of future standards.

And how they support what we're trying to do here at the agency and the utilization of standards for their intended purpose. Does that answer your questions?

(Charles Williams): Yes thank you.

Coordinator: And thank you. And our next questions from (Anthony Rogers). Your line's open.

(Anthony Rogers): Yes. Hello. Earlier this year there was a guidance that came out from FDA on complete test reports and summary test reports.

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I'd like to know if you can provide some clarity whether the summary test reports under the ASCA pilot program are envisioning yet an additional level of summarization. So then there would be three things that would be necessary rather than just two. Or whether it's going to be possible to harmonize the ASCA summary report with the summary report that's already expressed or laid out in recent guidance.

(Scott Colburn): Hi (Anthony) this is (Scott Colburn) again. I'll try to answer this the best that I can. That first guidance you referenced about the summary and complete test reports is really designed at those types of testing that is other than testing conducted to FDA recognized consensus standards.

The FDA recognized consensus standards is really designed and follows the out - construct of the appropriate use standards guidance that was referenced in this guidance document. The ASCA program is a bridge from that guidance describing where if you're using the selected standards that are in the pilot program in the appendix's that describe the level of evidence that would be needed to support a declaration conformity to those standards under this program, who that would be summarized effectively. The Guidance that you did refer to does discuss standards.

But from my understanding really points the direction at making sure that you are following the outlined guidance that is in the appropriate use of voluntary consensus standards. I hope that answers your question.

Coordinator: Thank you. Our next questions. I'm sorry go ahead (Anthony).

(Anthony Rogers): I hope it does too. Thank you.

Coordinator: Thank you. And our next question is from (Randy Long). Your lines open.

(Randy Long): Good afternoon. Thank you. I noticed the presentation for the requirement at 17025 for internal audits to be conducted annually which isn't actually required in 17025. And the draft documents we've been also seems to infer that. Is it the FDA's intent to require testing laboratories to conduct internal audits at least annually?

(Amy Cutts): Thank you very much for that question. The - I understand it the leverage existing audits and to not require anything additional except as those outlined in the ASCA program specifications.

Coordinator: Our next questions from (Merriam Usaf). Your lines open.

(Merriam Usaf): Hi this is (Merriam Usaf). I just wanted to clarify that is it the correct understanding that manufacturers own laboratories may participate in the program as well?

(Amy Cutts): Yes that's correct.

(Merriam Usaf): Thank you.

(Scott Colburn): And I'm going to put another pitch in for that as well. Because I know many manufacturers are not aware that their own testing laboratories can participate. And I would ask especially for those manufacturers who are coming from the regulatory affair side engage with your company to see, you know, do you have testing facilities of your own that are accredited.

And if so would they be able to meet the program specifications as outlined in the Guidance. And have that dialogue with them. Just make sure you guys are maximizing an opportunity to participate in the voluntary program.

Coordinator: Thank you. Our next questions is from (Dan Plunksy). Your line's open.

(Dan Plunksy): Yes hello. Thank you. Just a quick question has any thought been given to how this might overlap or coordinate with the CB scheme. For particularly for the 60601 series?

(Scott Colburn): So yes. We've engaged with the number of the stakeholders that are operating within the CB scheme and discussing with the IECCE how the test report forms and that system works. To be able to help us understand what would be the appropriate level of evidence to support a summary of say a TRF because that is not what FDA intends to want to review in a submission that is indicating an ASCA declaration of conformity so to speak. But we are looking at that. And we understand that that system has value of course on an international scale and supporting how those systems are used or the schemes are used internationally.

We also are hoping that with us engaging with the CB scheme and discussing with those stakeholders that they would have a regulatory perspective of seeing where they can make enhancements. And then how that system can, you know, further expand itself as an international scheme to serve the needs. But, you know, we have been working with them in trying to understand exactly how certain things such as essential performance filters itself into the scheme. And how that information is discussed and brought out from the testing that is conducted and brought out from the testing that is conducted by such entities.

(Dan Plunksy): Very good. Thank you.

Coordinator: Our next question is from (Andy Dorian). Your line's open.

(Andy Dorian): Yes thank you. (Andy Dorian) here. One question is I'm wondering if the additional requirements in the ASCA guidance appendix B are being considered for addition to the 17025 standard itself. Has the FDA participated in the development of that standard in the past? Or do they intend to in the future?

(Scott Colburn): Hi (Andy) this is (Scott) again. So while we haven't physically participated in the working group that did the 2017 update of that version we have been working closely with a number of our own stakeholders here within the Government. Mainly at NIST in the (unintelligible) Coordination Office where they do have personnel that have set on, have a wide range of experience in both the development structure of the different versions of that standard.

As well as implementing it into Federal Regulatory Schemes. So we have been educated along for the process. And have brought in experts to also educate the agency on that standard as well as 17011 and other areas.

So that theory is for us to become a little bit more first in this process. So we understand when writing additional program specifications where does that impact, why, and how we can inhale - when we receive comments to the Guidance how we can appropriately assess those to see how that impact will gain the value that we hope to get from this.

(Andy Dorian): Okay. Thank you (Scott).

Coordinator: And thank you. Once again if there's further questions on the phone line please press star followed by number 1. And our next question is (Leo Eisner). Your line's open.

(Leo Isnor): Thank you. My question is the interest level in the 60601 test labs and accreditation bodies, how many of those - the test labs have brought in interest - brought interest? Or have talked to FDA about wanting to be participants in the scheme at this point?

(Amy Cuts): We've had a large number of interest. And they've engaged from our workshop that we held. We had - I don't remember the exact number.

I know we have - I think we have a report up on our website. But we have had a large number of test labs that were interested and participated in our workshop there.

And I would hope that they would continue to be interested in participating in the pilot. Including providing comments to this draft Guidance document and hopefully participating when it goes final.

(Leo Isnor): Okay. Thank you.

Coordinator: And thank you. Once again if there's further questions from the phone line please press star followed by number 1. And at this time I'm seeing no further questions.

I'd like to turn the meeting over to Irene Aihie. Oh we do have a couple more questions. (Joel Kents) your line's open.

(Joe Kents): Yes. Thank you. Good afternoon. Thanks for the presentation.

I have a quick question about the appendix (unintelligible) so for the 60601 series. If we are submitting the declaration of conformity after we got our test results from the ASCA laboratory. There's also this summary of test results. I'm - first question is I'm presuming that those - that is something from a nature that it looks like it's something the manufacturer would fill out. And secondly my question is there's a number of, at least in the work we do, because of the nature of the standards there are many clauses that cannot be not applicable during these testing - the testing. And it appears like we have to list all those non-applicable clauses with rationale although they should be already in the test report that the ASCA laboratory has already provided us.

Is there any thoughts to, you know, having it stand it in the test report? And because it's a qualified laboratory we don't have to explain the non-applicable clauses? Or are we stuck with it.

Woman 3: I think understanding the non-applicable causes or clauses is a very important component for our review staff to feel confident in what was tested and what wasn't tested. So that's a - it's a component that we feel pretty strongly around in those proposed example summary test report. One thing I do want to clarify is that proposed summary test report is the only thing that's coming into FDA.

So it's not coming in two different things. It's not a complete test report and an example summary test report. We're just expecting to receive the example summary test report.

(Joe Kents): All right. Okay. Thank you.

Coordinator: We have a question (Karen Anthis) your line's open.

(Karen Anthis): Yes hello thank you. And thank you for the great presentation. It's really helpful.

I had a question about the scope of accreditation where it's referenced that as part of the application for approval of the testing review of their accredited scope will be done. I know a lot of accredited testing laboratories have multiple scopes. And they reference a lot of different methodologies. So if you could clarify do they have a separate scope that only lists the test methods that are going to be part of the ASCA pilot? Or will the FDA just look at their current scopes to confirm that different methods are present there? And secondly does compliance with the ASCA pilot requirements have to be listed on the scope? Or can the accreditation body confirm that separately?

(Amy Cutts): So I'll do my best to answer that question. So accreditation that would occur as part of the ASCA pilot would be a separate accreditation that would look at not just 17025 but also those ASCA program specification. So I would expect at what comes into an application request for recognition would clearly indicate that accreditation was conducted in accordance with both of those things. And list the test methods that were included in the assessment.

(Scott Colburn): Yes. And I'll add on to that. My suggestion would be for those who have testing laboratories or are testing laboratories themselves should be looking at their current scope of accreditation to see if those standards are those that may be those that they wish to have, you know, submitted as part of their scope if they wish to participate in the program.

But look at those program specifications that are outlined in the guidance. And compare that to their current procedures and how they're operating and documenting their use of ISO/IEC 17025. And have a discussion with their accreditation body to see where is their delta.

And what they need to do to prepare for such, you know, for, you know, that *ASCA Accreditation* so to speak. That will help them how understand how to prepare for that process. And then when they apply for *ASCA Accreditation* - or apply - or have accreditation from a participating accreditation body they would be able to probably have a lot -the lion's share of that work already done.

For example some laboratories who have already the guidance, have done the assessment, and determined that, you know, they feel that by and large they're meeting the additional program specifications in certain areas. And there's a few areas that they need to update or have communication with their AB to determine how they should be demonstrating such for them to be able to feel comfortable to have a positive assessment by an accreditation body. In hopes of being able to apply into the program.

So I would encourage laboratories to look at their current procedures and how they operate under ISO/IEC 17025. Compare that to the additional program specifications to the standards of which they may feel they want to participate in the scope of the program. And be able to work that process through now.

And then once the final Guidance publishes they will have, you know, I think a few steps already, you know, in the right direction. So they can make that final assessment prior to looking, engaging with the accreditation body.

(Karen Anthis): Great. Thank you all for the very helpful information.

Coordinator: Thank you. And we have a question from (Anthony Rogers). Your line's re-open.

(Anthony Rogers): Thank you. It was helpful to hear the comment that there is not an expectation to receive submission of full test reports as part of those submissions that include accredited summary test reports. That was a helpful comment.

Thank you. Related to that I wonder if you can describe the plan for collecting metrics on how many times the summary test reports result in the request, the need to request a full test report, or ask questions. And the reasons therefore to try to establish some metrics on the effectiveness and the benefit of the program please.

(Stacy Ohm): Hi (Anthony). Thank you for that great question. This is Stacy again.

So that is already encompassed in the statute in terms of having the pilot evaluation report being displayed in 2022. That's not to say that we're going to put it off until then. But one of the major things that we are doing is already finding different ways to have metrics that we can share with the public through the annual report that we'll be releasing every year

And so, you know, once we - again this is a pilot program so please bear with us as we kind of gauge the level of participation, the number of submissions. These are things that are out of our control. But one of the things that we certainly plan on doing is once the submission and the pilot get kicked off is to be able to evaluate the metrics of how this program is affecting pre-market submission. So this is definitely information that we will be sharing in the future.

(Anthony Rogers): Thank you.

Coordinator: And thank you. Once again if there's further questions on the phone line please press star followed by number 1. That is star followed by number 1. Please un-mute your line and record your name clearly as prompted.

Stacy Cho: While we're waiting I'll just remind everyone that this is draft guidance. And we look very much forward to any comments that you have. So please submit them to the docket.

Or to our email address. So we can make sure that this is the most successful program possible.

Coordinator: And I'm showing no further questions at this time. I'll turn the meeting over to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions.

Today's presentation and transcripts will be made available on the CDRH learning web page at www.fda.gov/training/cdrhlearn by Tuesday November 5th. If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation. As always we appreciate your feedback.

Following the conclusion of today's live webinar, please complete a short 13 question survey about your FDA CDRH webinar

experience. This survey can be found at www.fda.gov/cdrhwebinars immediately following the conclusion of today's live webinar. Again thank you for participating. This concludes today's webinar.

Coordinator: And thank you. This does conclude today's conference call. You may disconnect your lines. And thank you for your participation.

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